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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,356	11/21/2000	Shimpei Ushio	USHIO-2	8174

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/716,356	USHIO ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-94* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 6-9, and 18-61, drawn to purified polypeptides that induce interferon-γ production (polypeptides), fragments and homologues thereof, and pharmaceutical compositions comprising them, classified in class 424, subclass 185.1.

II. Claims 80-89, drawn to polynucleotides, recombinant DNA molecules, and host cells transformed by the DNA molecules that encode for the polypeptides, classified in class 536, subclass 23.5.

III. Claims 90-91, drawn to a process of preparing the polypeptides, classified in class 435, subclass 69.1.

IV. Claims 10-18, 62-79, and 93 drawn to methods of using the polypeptides in treatment of diseases, classified in class 514, subclass 889.

V. Claims 92-93, drawn to methods of using antibodies to neutralize the polypeptides, classified in class 424, subclass 141.1.

VI. Claim 94, drawn to hybridoma cells that produce antibodies to the polypeptides, classified in class 530, subclass 809.

For Invention IV above, restriction to one of the following is also required under 35 U.S.C. 121. Therefore, election is required of one of the inventions I to VI, and if IV is chosen, to one of the below inventions (A)-(E)

(A). a method of treating viral diseases,

(B) a method of treating bacterial diseases,

(C) a method of treating immune diseases,

(D) a method of treating atopic diseases, and

(E) a method of treating cancers.

The inventions are distinct, each from the others, for the following reasons:

2. Inventions (A) to (E) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relate to the treatment of different diseases. In each case the same polypeptide is disclosed as being used to treat a different disease. However, the different treatments are not disclosed as being usable together. Further, because different diseases are being treated in each of the methods, different effects are being achieved by each method- the treatment of a different type of disease. Since the different disease types are generally expected to require different forms of treatment (e.g. antibiotics for bacterial infections, vaccines for viral diseases, and various forms of treatment for immune diseases and cancer), each of the methods of treatment disclosed in the application requires comparison to a different set of disease treatments- and is thus materially distinct from the other methods. The inventions are therefore unrelated.

3. Inventions I and III-VI; and invention II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relate to polypeptides, methods of using them, methods of

neutralizing them, and cells producing antibodies thereto; and to DNA molecules and host cells transformed by the DNA molecules. The inventions are not disclosed as usable together. Further the DNA molecules perform different functions from the polypeptides and operate in a different manner. The polypeptides are disclosed as primarily for use in treating diseases by stimulating the production of interferon-γ. The only disclosed uses for the polyneucleotides are to encode for, and for use in processes to produce, the polypeptides. Thus, the polynucleotide inventions perform different functions from those with polypeptides. The polynucleotides have no disclosed connection to the uses of antibodies to neutralize the polypeptides, or to the hybridoma cells that produce the antibodies. The DNA inventions are therefore distinct from the other inventions.

4. Invention VI is unrelated to inventions I and III-IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relate to hybriboma cell lines capable of producing antibodies to claimed polypeptides, and to polypeptides and methods of using and producing the same. The hybridoma cells are not disclosed as being usable with the polypeptides, or their use or production. The purpose of the cells is to produce antibodies to the polypeptides, but are themselves not used with the polypeptides. Further, the cells perform different functions from the polypeptides, and methods of using and making the polypeptides. The inventions are therefore unrelated.

5. Inventions VI and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

inventions relate to hybridoma cells for producing antibodies to the claimed polypeptides, and to methods of using the antibodies. The inventions are not disclosed as usable together. The cells used to make antibodies are not disclosed as usable with the method of neutralizing the claimed polypeptides by contacting them with antibodies. Further, while the antibodies used in the method may be produced by the hybridomas, those cells are not the only source of antibodies that may be used in the method. Thus the hybridomas, and the methods of neutralizing polypeptides by contacting them with antibodies are unrelated and distinct inventions.

6. Inventions I and V are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product of invention I is deemed to be useful in the treatment of several diseases, while invention V relates to a method of combining the polypeptide with an antibody thereby making an apparently inactive protein. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions I and V are also related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the polypeptide is usable in other processes than its own neutralization. It is also disclosed as being usable in the treatment of diseases. Inventions I and V are therefore distinct.

7. Invention V, and inventions II-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions relate to a method of combining an antibody with a polypeptide, and to other methods of using the polypeptide, methods of making the polypeptide, and polynucleotides encoding the polypeptide. The method using the antibodies is not disclosed as usable with any other methods of using the polypeptide, and has no connection to the making of, or the polynucleotides encoding for, the polypeptide. Further, contacting the polypeptide with an antibody to neutralize has all a different function, mode of operation, and effect from methods of using the polypeptide to treat diseases. Invention V is therefore distinct from the other named inventions.

8. Inventions I and IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case invention I describes a polypeptide, and invention IV describes several methods of using said polypeptide for treating in various unrelated diseases. The methods cover methods of treating multiple types of diseases, such as viral, bacterial, and immune diseases, as well as various forms of cancer. It is known in the art that treatment of these

different types of diseases generally entails different approaches and methods of treatment (e.g. bacteria usually treated with antibacterial, viral diseases often treated by vaccination, and no one effective treatment has been developed for immune diseases). Thus, treatment of any one of those diseases is materially different from treatment of the others, and would require a separate art and literature search. Thus, the product is usable in several materially different processes. The inventions are therefore distinct.

9. Inventions I and III are related as product made and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case invention 1 is to a group of polypeptides, and invention III describes a method of producing them through recombinant cell expression. The polypeptides of invention I can be produced through other process than recombinant cell expression; for example by purifying it from a natural source. See App., p. 9, lines 13-16. Because the product can be made by two or more materially different processes, the product and the claimed process of making it are distinct.

10. Inventions I, III and IV are related as product, process of use, and process of making. Inventions in this relationship can be shown to be distinct if the product can be shown to be distinct from both the process of using and the process of making (MPEP 806.05(i)). The inventions in this case relate to a polypeptide, methods of using the polypeptide, and a process of making the polypeptide. As is shown above, the product claims have been shown to be distinct from both the process of making the polypeptide and the process of using it. See ¶¶ 8-9 above.

For those reasons, the product, process of making, and process of using inventions in this application are distinct.

11. Because these inventions are distinct for the reason given above, have acquired a separate status in art because of recognized divergent subject matter and different classifications, and because the literature and sequence searches required for any one of the groups is not required for the others, restriction for examination purposes as indicated is proper.

12. Applicant is advised that in order for the reply to this requirement to be complete, it must include an election of an invention to be examined as described above, even if the requirement is traversed (37 CFR 1.143).

13. Applicant's attention is hereby directed to the following is a recitation of M.P.E.P. §821.04 regarding the restriction of claims to a product and processes of using the product, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02© and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
>
> Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either (1) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2), or (2) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2), even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26 states that "[m]oney paid by actual mistake or in excess will be refunded, but a mere change of purpose after the payment of money...will not entitle a party to demand such a return..." The fees paid under 37 CFR 1.129(b) were not paid by actual mistake nor paid in excess, therefore, applicant would not be entitled to a refund.
>
> In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

In accordance with M.P.E.P. §821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
March 6, 2002

JAMES HOUSEL 3/11/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600